K123018

510(k) Summary

APR 2 3 2013

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	April 8, 2013	
Device:	Trade Name:	ACE Alera Clinical Chemistry System
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C.F.R. § 862.2160) Product Code JJE
	Trade Name:	ACE Glucose Reagent
	Classification:	Class 2
	Common/Classification Name:	Hexokinase, Glucose (21 C.F.R. § 862.1345) Product Code CFR
	Trade Name:	ACE Ion Selective Electrode (ISE) Module
	Classification:	Class 2
	Common/Classification Name:	Electrode, Ion Specific, Sodium, Potassium, Chloride (21 C.F.R. § 862.1665, 862.1600, 862.1170) Product Codes JGS, CEM, CGZ
Predicate Devices:	Manufacturer for reagent system predicates: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Reagents (K930140, K933862)	

Device Descriptions:	The ACE Alera Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative determination of general chemistry assays for clinical use in physician office laboratories or clinical laboratories. The ACE Alera Clinical Chemistry System consists of a bench-top analyzer and an internal computer. The bench-top analyzer includes a single pipettor (syringe module/fluid arm/probe), a temperature-controlled reagent compartment, a reaction wheel and a holographic diffraction grating spectrophotometer. In the ACE Glucose Reagent assay, glucose in serum or heparin plasma reacts with adenosine triphosphate in the presence of hexokinase and magnesium with the formation of glucose-6-phosphate and adenosine diphosphate. Glucose-6-phosphate dehydrogenase catalyzes the oxidation of glucose-6-phosphate with NAD^+ to form 6-phosphogluconate and NADH. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. The total amount of NADH formed is proportional to the concentration of glucose in the sample. The increase in absorbance is measured bichromatically at 340 nm/378 nm. The ACE Ion Selective Electrode (ISE) Module, as part of the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems, uses a potentiometric method via ion-specific electrodes to simultaneously measure sodium, potassium and chloride in undiluted serum. Ion-specific membranes measure the difference in ionic concentrations between an inner electrolyte solution and the sample. The connection of the amplifier and ground (reference electrode) to the ion selective electrode forms the measuring system. A two-point calibration utilizes ACE CAL A and CAL B undiluted ISE Calibration Solutions with precisely known ion concentrations. The measured voltage difference of the sample and the CAL A and CAL B solutions determines the ion concentration in the sample on the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems.
Intended Use:	Indications for Use: The ACE Alera Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative measurement of general chemistry assays, such as glucose, sodium, potassium, and chloride, for clinical use in physician office laboratories or clinical laboratories. • Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. • Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. • Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. • Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

	ACE Glucose Reagent is intended for the quantitative determination of glucose in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE Ion Selective Electrode (ISE) module on the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems is used to measure concentrations of sodium, potassium, and chloride in undiluted serum and lithium heparin plasma. • Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. • Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. • Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	The ACE Glucose Reagent consists of a single reagent bottle. The reagent contains nicotinamide adenine dinucleotide (NAD), adenosine 5'-triphosphate (ATP), magnesium, hexokinase and glucose-6-phosphate dehydrogenase. ACE ISE Module CAL A and CAL B Undiluted ISE Calibration Solution contain known levels of sodium, potassium and chloride.

Device Comparison with Predicate

ACE Alera Clinical Chemistry System

Comparison of similarities and differences:

	Candidate Device	Predicate Device K113253 (ACE Axcel System)
Intended Use/ Indications for Use	Clinical chemistry analyzer intended for the quantitative measurements of general chemistry assays. For use in clinical laboratories or physician office laboratories.	Same
Instrument Platform	ACE Alera Clinical Chemistry System	ACE Axcel Clinical Chemistry System
Method of measurements	Potentiometric (ISE) and photometric chemistries	Same
Calibration	same	Automatic
Calibration Stability	same	3 hrs. STAT READY, as required after 3 hrs. STANDBY. When solution lot numbers are changed, new electrodes are installed, major service is performed or a control shift warrants
Sample Volume	same	156 µL
ISE Type	same	Direct (undiluted)

ACE Ion Selective Electrode (ISE) Module

Comparison of similarities and differences:

	Candidate Device	Predicate Device ACE Clinical Chemistry Syste With ISE (k933862)
Intended Use/Indications for Use	For the quantitative measurements of sodium, potassium, and chloride in human serum and lithium heparin plasma	Same
Method	Potentiometric: Ion-selective electrode	Same
Sample Type	Serum and lithium heparin plasma	Serum
Expected Values	Na: 136-145 mmol/L K: 3.5-5.1 mmol/L Cl: 98-107 mmol/L	Same
Measuring range	Na 40-205 mmol/L K 1.5-15 mmol/L Cl 50-200 mmol/L	Same

ACE Glucose Reagent

Comparison of similarities and differences:

GLUCOSE	Candidate Device	Predicate Device k930104 (ACE Glucose Reagent)
Intended Use/Indications for Use	For the quantitative measurement of glucose in human serum and lithium heparin plasma	Same
Method	Photometric	Same
Sample Type	Serum and lithium heparin plasma	Serum
Expected value	70-105 mg/dL	Serum
Measuring range	4-750 mg/dL	3-750 mg/dL

Performance Data:

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Alera Clinical Chemistry System includes the following data:

Precision (SD, %CV)						
Glucose mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**
Serum Low	58	0.6, 1.1%	0.8, 1.4%	62	0.6, 0.9%	0.8, 1.3%
Serum Mid	158	1.4, 0.9%	2.6, 1.7%	121	1.2, 1.0%	1.5, 1.3%
Serum High	273	2.5, 0.9%	3.1, 1.2%	366	6.4, 1.8%	6.9, 1.9%
Sodium mmol/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**
Serum Low	111.4	0.63, 0.6%	0.93, 0.8%	111.2	0.59, 0.5%	0.93, 0.8%
Serum Mid	139.1	1.14, 0.8%	1.14, 0.8%	139.0	0.80, 0.6%	0.87, 0.6%
Serum High	159.7	0.56, 0.4%	0.74, 0.5%	159.9	0.38, 0.2%	0.90, 0.6%
Potassium mmol/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**
Serum Low	2.1	0.02, 1.0%	0.04, 1.6%	2.2	0.04, 1.6%	0.05, 2.4%
Serum Mid	3.9	0.08, 2.0%	0.08, 2.0%	4.0	0.07, 1.8%	0.07, 1.8%
Serum High	7.9	0.07, 0.9%	0.09, 1.2%	7.9	0.07, 0.9%	0.11, 1.4%
Chloride mmol/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**
Serum Low	74.7	0.50, 0.7%	1.00, 1.3%	75.0	0.80, 1.1%	1.50, 2.0%
Serum Mid	99.1	0.70, 0.7%	0.80, 0.8%	99.2	0.80, 0.8%	0.90, 0.9%
Serum High	119.3	0.50, 0.4%	0.80, 0.7%	119.3	0.50, 0.4%	1.10, 0.9%

POL Precision

Glucose		ACE SD (mg/dL) or %CV			ACE Alera SD (mg/dL) or %CV		
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	63.5	1.0 SD 1.6%	1.2 SD 1.9%	62.5	1.2 SD 1.9%	1.3 SD 2.1%
POL 1	1	62.7	0.6 SD 1.0%	1.1 SD 1.7%	64.3	1.1 SD 1.7%	1.5 SD 2.3%
POL 2	1	62.5	0.8 SD 1.3%	1.3 SD 2.1%	65.3	0.6 SD 0.9%	0.9 SD 1.3%
POL 3	1	63.2	0.8 SD 1.3%	1.1 SD 1.8%	64.7	0.5 SD 0.8%	1.0 SD 1.5%
In-House	2	305.7	1.3 SD 0.4%	2.4 SD 0.8%	300.0	2.4 SD 0.8%	4.0 SD 1.3%
POL 1	2	292.8	3.7 SD 1.3%	4.7 SD 1.6%	292.1	4.7 SD 1.6%	6.6 SD 2.3%
POL 2	2	298.4	2.6 SD 0.9%	4.9 SD 1.6%	296.6	4.6 SD 1.6%	8.1 SD 2.7%
POL 3	2	289.4	2.0 SD 0.7%	4.5 SD 1.6%	294.2	2.1 SD 0.7%	4.3 SD 1.5%
In-House	3	541.1	5.0 SD 0.9%	7.3 SD 1.3%	529.8	5.2 SD 1.0%	12.6 SD 2.4%
POL 1	3	508.4	9.2 SD 1.8%	13.1 SD 2.6%	500.7	11.5 SD 2.3%	13.8 SD 2.8%
POL 2	3	522.3	8.7 SD 1.7%	11.8 SD 2.3%	513.6	12.4 SD 2.4%	13.9 SD 2.7%
POL 3	3	506.8	3.1 SD 0.6%	8.4 SD 1.7%	508.8	4.2 SD 0.8%	6.5 SD 1.3%

Sodium		ACE SD (mmol/L) or %CV			ACE Alera SD (mmol/L) or %CV		
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	108.1	0.72 SD 0.7%	0.95 SD 0.9%	107.5	0.80 SD 0.7%	1.50 SD 1.4%
POL 1	1	108.7	1.20 SD 1.1%	1.80 SD 1.6%	108.4	0.93 SD 0.9%	1.44 SD 1.3%
POL 2	1	108	0.90 SD 0.9%	1.70 SD 1.6%	108.1	0.94 SD 0.9%	1.16 SD 1.1%
POL 3	1	109.6	0.60 SD 0.6%	0.90 SD 0.8%	107.0	0.56 SD 0.5%	0.98 SD 0.9%
In-House	2	149.2	0.53 SD 0.4%	0.65 SD 0.4%	149.2	0.60 SD 0.4%	0.70 SD 0.5%
POL 1	2	146.9	1.20 SD 0.8%	1.20 SD 0.8%	148.7	1.41 SD 0.9%	1.72 SD 1.2%
POL 2	2	149.4	1.00 SD 0.7%	1.00 SD 0.7%	146.1	0.56 SD 0.4%	0.80 SD 0.5%
POL 3	2	147.6	1.00 SD 0.7%	1.30 SD 0.9%	147.6	0.95 SD 0.6%	0.95 SD 0.6%
In-House	3	196.4	2.07 SD 1.1%	2.58 SD 1.3%	197.1	1.80 SD 0.9%	2.10 SD 1.1%
POL 1	3	190.2	1.70 SD 0.9%	1.90 SD 1.0%	193.7	1.33 SD 0.7%	2.74 SD 1.4%
POL 2	3	197.4	1.20 SD 0.6%	2.60 SD 1.3%	189.4	0.80 SD 0.4%	1.31 SD 0.7%
POL 3	3	190.6	0.80 SD 0.40%	1.70 SD 0.9%	192.7	1.09 SD 0.6%	1.09 SD 0.6%

Potassium		ACE SD (mmol/L) or %CV			ACE Alera SD (mmol/L) or %CV		
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	3.72	0.05 SD 1.2%	0.05 SD 1.3%	3.70	0.06 SD 1.6%	0.06 SD 1.7%
POL 1	1	3.78	0.09 SD 2.4%	0.09 SD 2.5%	3.73	0.07 SD 1.8%	0.08 SD 2.2%
POL 2	1	3.71	0.02 SD 0.6%	0.02 SD 0.6%	3.77	0.06 SD 1.7%	0.07 SD 1.8%
POL 3	1	3.76	0.07 SD 1.8%	0.07 SD 1.8%	3.73	0.05 SD 1.3%	0.06 SD 1.6%
In-House	2	6.52	0.13 SD 2.0%	0.13 SD 2.0%	6.56	0.13 SD 2.0%	0.14 SD 2.1%
POL 1	2	6.68	0.08 SD 1.2%	0.09 SD 1.4%	6.89	0.13 SD 1.8%	0.16 SD 2.4%
POL 2	2	6.49	0.05 SD 0.8%	0.05 SD 0.8%	6.70	0.08 SD 1.2%	0.09 SD 1.3%
POL 3	2	6.74	0.07 SD 1.0%	0.07 SD 1.0%	6.67	0.05 SD 0.8%	0.10 SD 1.4%
In-House	3	9.56	0.11 SD 1.1%	0.17 SD 1.8%	9.73	0.09 SD 0.9%	0.19 SD 2.0%
POL 1	3	9.90	0.21 SD 2.2%	0.22 SD 2.2%	10.36	0.08 SD 0.8%	0.19 SD 1.8%
POL 2	3	9.56	0.07 SD 0.8%	0.11 SD 1.2%	10.04	0.04 SD 0.4%	0.19 SD 1.9%
POL 3	3	10.08	0.06 SD 0.6%	0.11 SD 1.1%	9.92	0.15 SD 1.5%	0.22 SD 2.2%

Chloride		ACE SD (mmol/L) or %CV			ACE Alera SD (mmol/L) or %CV		
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	77.6	0.37 SD	0.69 SD	77.3	0.50 SD	1.20 SD
			0.5%	0.9%		0.6%	1.6%
POL 1	1	79.2	1.40 SD	1.70 SD	78.1	0.76 SD	1.30 SD
			1.8%	2.1%		1.0%	1.7%
POL 2	1	78.1	0.60 SD	0.70 SD	78.4	0.89 SD	1.24 SD
			0.8%	0.9%		1.1%	1.6%
POL 3	1	79.1	0.90 SD	1.20 SD	78.1	0.48 SD	0.54 SD
			1.1%	1.5%		0.6%	0.7%
In-House	2	108.2	1.33 SD	1.40 SD	108.3	1.20 SD	1.30 SD
			1.2%	1.3%		1.1%	1.2%
POL 1	2	108.1	0.70 SD	0.80 SD	109.0	1.42 SD	1.42 SD
			0.7%	0.7%		1.3%	1.3%
POL 2	2	107.3	0.40 SD	0.50 SD	107.7	0.69 SD	0.85 SD
			0.4%	0.5%		0.6%	0.8%
POL 3	2	108.2	0.80 SD	1.10 SD	108.2	0.60 SD	0.67 SD
			0.7%	1.0%		0.6%	0.6%
In-House	3	142.0	1.59 SD	1.81 SD	143.4	1.70 SD	1.80 SD
			1.1%	1.3%		1.2%	1.3%
POL 1	3	140.5	1.50 SD	1.60 SD	142.8	1.11 SD	2.04 SD
			1.1%	1.2%		0.8%	1.4%
POL 2	3	139.8	0.70 SD	1.10 SD	141.2	0.73 SD	1.69 SD
			0.5%	0.8%		0.5%	1.2%
POL 3	3	140.1	0.60 SD	1.10 SD	142.2	0.61 SD	0.75 SD
			0.5%	0.8%		0.4%	0.5%

Interferences

ACE Alera	Icterus	Hemolysis	Lipemia (Intralipid) (Turbidity)	Lipemia (Triglycerides) (Avian)	Ascorbic Acid
GLU	No significant interference at or below 26 mg/dL	No significant interference at or below 1000 mg/dL	No significant interference at or below 104 mg/dL	No significant interference at or below 525 mg/dL	No significant interference at or below 6 mg/dL
NA	No significant interference at or below 50 mg/dL	No significant interference at or below 1000 mg/dL	No significant interference at or below 125 mg/dL	No significant interference at or below 656 mg/dL	No significant interference at or below 6 mg/dL
K	No significant interference at or below 50 mg/dL	No significant interference at or below 125 mg/dL	No significant interference at or below 125 mg/dL	No significant interference at or below 420 mg/dL	No significant interference at or below 6 mg/dL
CL	No significant interference at or below 50 mg/dL	No significant interference at or below 1000 mg/dL	No significant interference at or below 125 mg/dL	No significant interference at or below 420 mg/dL	No significant interference at or below 6 mg/dL

Method Comparison Data-Ace vs. Alera POL's

Glucose	mg/dL	ACE *Alera*		
		POL 1	POL 2	POL 3
Method Comparison: ACE system In-House vs. ACE Alera system POL (2012 Data)	n	46	46	46
	Range (mg/dL)	22-625	22-625	22-625
	Slope	1.015	1.005	0.988
	Intercept	0.1	3.1	3.2
	Correlation Coefficient	0.9993	0.9995	0.9993
	Std. Error	4.8	3.9	4.4
	CI Slope	1.003 to 1.027	0.995 to 1.015	0.978 to 0.999
	CI Intercept	-2.2 to 2.3	1.3 to 4.9	1.1 to 5.2

Sodium	mmol/L	ACE *Alera*		
		POL 1	POL 2	POL 3
Method Comparison: ACE system In-House vs. ACE Alera system POL (2012 Data)	n	42	42	42
	Range (mmol/L)	51-202	51-202	51-202
	Slope	1.025	1.021	1.044
	Intercept	-1.74	-2.92	-6.27
	Correlation Coefficient	0.9974	0.9958	0.9979
	Std. Error	2.05	2.59	1.87
	CI Slope	1.001 to 1.049	0.991 to 1.051	1.022 to 1.065
	CI Intercept	-5.04 to 1.55	-7.08 to 1.24	-9.27 to -3.27

Potassium	mmol/L	ACE *Alera*		
		POL 1	POL 2	POL 3
Method Comparison: ACE system In-House vs. ACE Alera system POL (2012 Data)	n	43	43	43
	Range (mmol/L)	1.8-13.7	1.8-13.7	1.8-13.7
	Slope	1.032	1.008	0.984
	Intercept	-0.108	-0.054	0.150
	Correlation Coefficient	0.9983	0.9971	0.9942
	Std. Error	0.131	0.166	0.230
	CI Slope	1.013 to 1.051	0.984 to 1.032	0.951 to 1.018
	CI Intercept	-0.212 to -0.005	-0.185 to 0.077	-0.031 to 0.332

Chloride	**mmol/L**	**ACE *Alera***		
Method Comparison: ACE system In-House vs. ACE Alera system POL (2012 Data)		**POL 1**	**POL 2**	**POL 3**
	n	41	41	41
	Range (mmol/L)	59-187	59-187	59-187
	Slope	1.004	1.000	1.006
	Intercept	0.96	0.29	0.16
	Correlation Coefficient	0.9972	0.9956	0.9946
	Std. Error	1.69	2.11	2.35
	CI Slope	0.980 to 1.028	0.970 to 1.030	0.972 to 1.040
	CI Intercept	-1.68 to 3.60	-3.02 to 3.60	-3.52 to 3.85

Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence for lithium heparin plasma sample collection tubes to the predica device's use of serum sample collection tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2013

Alfa Wasserman Diagnostic Technologies, LLC
C/O Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K123018
Trade/Device Name: ACE Alera Clinical Chemistry System
ACE Glucose Reagent
ACE Ion Selective Electrode (ISE) Module
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR, JGS, CEM, CGZ, JJE
Dated: February 27, 2013
Received: March 5, 2013

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123018

Device Name: ACE Alera Clinical Chemistry System, ACE Glucose Reagent, ACE Ion Selective Electrode (ISE) Module

Indications for Use:
The ACE Alera Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative measurement of general chemistry assays, such as glucose, sodium, potassium, and chloride, for clinical use in physician office laboratories or clinical laboratories.

- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
- Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance.
- Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
- Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

ACE Glucose Reagent is intended for the quantitative determination of glucose in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D)	AND/OR	Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k) k123018

Indications for Use

510(k) Number (if known): __k123018_____

The ACE Ion Selective Electrode (ISE) module on the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems is used to measure concentrations of sodium, potassium, and chloride in undiluted serum and lithium heparin plasma.

- Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance.
- Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
- Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k)__k123018_____